

K003734 SERUM PROTEIN SUBSTITUTEDec 21, 2000
17 days to decisionK003734 · Product code: **MQL** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k003734/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Media, Reproductive (MQL)
Date received	Dec 4, 2000
Decision date	Dec 21, 2000
Days to decision	17 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Sage Biopharma
Location	Irvine, CA, US
Contact	GRACE HOLLAND
510(k) history	6 submissions · 6 cleared · 1999-2000

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003734/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026